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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/435,504	11/06/1999	DENNIS SUNGA FERNANDEZ	FERN-P006	5319

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EXAMINER	
RINES, ROBERT D	
ART UNIT	**PAPER NUMBER**
3623	
MAIL DATE	**DELIVERY MODE**
06/07/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/435,504	FERNANDEZ, DENNIS SUNGA	
	Examiner	Art Unit	
	R. David Rines	3623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 December 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12 and 21-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12 and 21-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Notice to Applicant

[1] This communication is in response to the amendment filed 15 December 2009. Claims 13-20 have been cancelled. Claims 1, 27, and 28 have been amended. Claims 1-12 and 21-28 are pending.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

[2] Claims 1-12 and 21-28 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 1 as presently amended recites "…wherein the bioinformatic value is automatically determined using a non-discriminatory sample sequence or index for predictably analyzing the voluntarily-selected portion of personal generic nucleotide sequence and related protein folding structure profile to enable transaction evaluation predictably according to actual user protein folding structure….".

The Specification as originally filed fails to provide written description of a system/method for performing the above noted automatic generation of a value by analyzing a genetic nucleotide sequence. Disclosure with respect to the above noted value determination is limited to discussion of alignment of sequences with a reference sequence or genome "map". However, merely determining a sequence variant against a reference sequence does not ensure a determination of a causal relationship between a sequence variant and a disease predisposition such that the claimed "bioinformatic value" of predictive utility can be "automatically determined". The Specification fails to provide any disclosure of genotype-phenotype correlation such that an individual's genetically-based susceptibility to a disease can be determined. Accordingly, the Specification as originally filed fails to provide sufficient evidence that Applicant was in possession of a method/system in which a value can be automatically determined such that a prediction of an individual's susceptibility to a disease can be attributed to a sequence variant present in the individual's genotype or a related protein conformational change/folding structure, i.e., "personal genetic sequence".

Claims 27 and 28, when analyzed in the manner described above with respect claim 1 above also recite subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 2-12 and 21-26 inherit and fail to remedy the deficiencies of claim 1 through dependency and are accordingly rejected under 35 U.S.C. 112, first paragraph, for claiming subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

[3] Claims 1, 10-12, 21, 27, and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Holden (United States Patent #6,640,211) in view of Messier et al. (United States Patent #6,228,586).

The unamended limitations in claims 1, 10-12, 21, 27, and 28 are rejected/addressed by the teachings of Holden as presented in the previous Office Action mailed 8 December 2009 and as indicated in the Decision of the Board of Patent Appeals and Interferences mailed 6 March 2006.

Claim 1 has been amended to further recite "…wherein the bioinformatic value is automatically determined using a non-discriminatory sample sequence or index for predictably analyzing the voluntarily-selected portion of personal generic nucleotide sequence and related protein folding structure profile to enable transaction evaluation predictably according to actual user protein folding structure…."

With respect to this feature, Holden discloses a voluntarily submission and authorized access to a patient's DNA sequence and genetic profile. Holden further discloses comparison of patient DNA sequence and specific SNP's are correlated to disease phenotypes (Holden; col. 3, lines 52-67 and col. 4, lines 34-60). Holden fails to provide and example of a genotypic and proteomic analysis to produce a correlation.

However, as evidenced by Messier et al. it is well known in the art that particular genotypic variances are related to peptide sequence differences/protein peptide sequence and

conformational changes. Further, it is well known to perform disease predisposition analyses which include analysis of nucleotide sequence markers and a conformational/sequence change in the associated protein (Messier et al.; col. 8, lines 16-52 and col. 10, lines 5-35).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the SNP/DNA sequence comparison methods disclosed by Holden with the well known practice of translating DNA sequence into peptide sequence to determine a change in the protein as disclosed by analogous reference Messier et al. The motivation to make the noted modification would have been to identify significant sequence changes that can be utilized in the development of treatments for human conditions or diseases.

Claims 27 and 28 as presented repeat the limitations of amended claim 1. Accordingly, claims 27-28 are rejected for the reasons, conclusion of obviousness, and statements of motivation as discussed above with respect to claim 1.

Claims 2-4, 6-9, and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Holden in view of Messier et al. as applied to claim 1 above, and further in view of "Genetic Tests: Evolving Policy Question" by Asch, as presented in the previous Office Action mailed 8 December 2009 and as indicated in the Decision of the Board of Patent Appeals and Interferences mailed 6 March 2006.

The unamended limitations in claims 2-4, 6-9, and 22 are rejected/addressed by the teachings of Holden in view of "Genetic Tests: Evolving Policy Question" by Asch as presented in the previous Office Action mailed 8 December 2009 and as indicated in the Decision of the Board of Patent Appeals and Interferences mailed 6 March 2006.

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Holden (United States Patent #6,640,211) in view of Messier et al. (United States Patent #6,228,586) as applied to claim 1 above, and further in view of O'Flaherty (United States Patent #6,275,824), as presented in the previous Office Action mailed 8 December 2009 and as indicated in the Decision of the Board of Patent Appeals and Interferences mailed 6 March 2006.

The unamended limitations in claims 2-4, 6-9, and 22 are rejected/addressed by the teachings of Holden in view of O'Flaherty as presented in the previous Office Action mailed 8 December 2009 and as indicated in the Decision of the Board of Patent Appeals and Interferences mailed 6 March 2006.

Response to Remarks

Applicant's remarks filed 15 December 2010 have been fully considered but moot in view of newly added grounds of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to R. David Rines whose telephone number is (571)272-5585. The examiner can normally be reached on 8:30am - 5:00pm Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Beth Boswell can be reached on 571-272-6737. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/R. David Rines/
Primary Examiner, Art Unit 3623